



K964370

GE Medical Systems

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P.O. Box 414, W-709
Milwaukee, WI 53201
USA**SUMMARY OF SAFETY AND EFFECTIVENESS**

- ° This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- ° Identification of Submitter

Larry A. Kroger, Ph.D., 414-544-3894, November 1, 1996

- ° Identification of the Product

Signa Contour 2 Magnetic Resonance System

Manufactured by: GE Yokogawa Medical Systems, Ltd.
4-7-127, Asahigaoka, Hino-shi
Tokyo, 191 Japan

- ° Marketed Devices

The Signa Contour 2 MR System with new 0.5T magnet is substantially equivalent to the currently marketed Signa Contour System (software and electronics).

- ° Device Description

The Signa Contour 2 System utilizes a superconducting magnet to acquire 2D single-slice and multi-slice, and 3D volume images. A wide variety of pulse sequences is provided to the operator, including inversion recovery, spin echo, gradient echo, gradient recalled, and steady state, free precession acquisitions. Imaging options such as cardiac gating, peripheral gating, flow compensation and fat/water suppression are provided to suppress artifacts due to physiological motion and improve image quality. The system can be used as a stationary or mobile system.

- ° Indications for Use

The Signa Contour 2 System is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head or body. The images produced reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.



SUMMARY OF SAFETY AND EFFECTIVENESS

- **Comparison with Predicate**

The magnets used with the Signa Contour 2 System are 45 Kg lighter and has a zero cryogen boil off rate as compared to 0.075 liters per hour for the Signa Contour System.

- **Summary of Studies**

The Signa Contour 2 System was evaluated to the appropriate NEMA performance standards as well as the IEC 601-1 International medical equipment safety standard. The Signa Contour 2 System is comparable to the Signa Contour MR System.

- **Conclusions**

It is the opinion of GE that the Signa Contour 2 System is substantially equivalent to the Signa Contour MR Systems. The Signa Contour 2 does not include any new indications for use, nor does use of this device result in any new potential hazards.